

**REMARKS/ARGUMENTS**

Applicants submit the aforementioned amendments and following remarks in response to the Final Office Action mailed October 18, 2007.

A petition for a three (3) month extension of time for responding to the Official Action is simultaneously filed herewith.

A Request For Continued Examination (RCE) is also being filed concurrently herewith.

Claims 2 and 5 are pending. Claims 2 and 5 have been amended.

Reconsideration is respectfully requested in view of the above amendments and the following remarks.

**Rejections under 35 U.S.C. § 112, second paragraph**

Claims 2 and 5 were rejected under 35 U.S.C. § 112, second paragraph, as being indefinite. In response to the Office Action, Applicants have amended claims to specify the position of the mutated amino acid and the sequence order of the method steps.

Accordingly, the rejection under 35 U.S.C. § 112, second paragraph has been overcome and should be withdrawn.

**Rejections under 35 U.S.C. § 112, first paragraph**

Claims 2 and 5 were rejected under 35 U.S.C. § 112, first paragraph. The Examiner maintained the rejection as claims containing subject matter not described in the specification commensurate in scope. However, in the last Office Action mailed March 7, 2007, the Examiner has withdrawn the same rejection to claim 2 in view of the amendment submitted December 20, 2006. See Office Action mailed March 7, 2007, page 4. Afterward, claim 2 is only amended to address indefinite and new matter rejections. The amendment includes “mutation at the position of 194 wherein the wild type amino acid is mutated to glycine” in step (ii), “said ~~mutated~~ HIV reserves transcriptase” in steps (iii) and (iv), and “effectiveness of said inhibitor in samples containing ~~the~~ said reverse transcriptase mutation 194G” in step (v). See Response submitted August 17, 2007, page 2. Such amendment has not altered the

scope of claim 2. Hence, Applicants are not clear about the ground of the ‘maintained’ rejection to claim 2. Applicants respectively request further clarification from the Examiner.

With regard to the rejection to claim 5, Applicants have amended the claim to limit the scope to a method for evaluating a change in susceptibility of an HIV reverse transcriptase inhibitor. Accordingly, the rejection has been overcome and should be withdrawn.

**Rejection under 35 U.S.C. § 103(a)**

Claims 2 and 5 are further rejected under 35 U.S.C. § 103(a) over Stein et al, 1994 in view of Servais et al, 2001.

Stein et al. discloses a use of the end point dilution PCR method, which is used to directly isolate and to sequence reverse transcriptase DNA from patients undergoing an AZT treatment. See Abstract, page 115. The results show a heterogeneous mixture of reverse transcriptase mutations that are present in the patients. These reverse transcriptase mutations are compared with those from patients who did not receive the treatment of AZT or patients prior to receiving the treatment of AZT. See page 116, Table 1.

AZT is not a reverse transcriptase inhibitor. The mechanism of inhibiting HIV infection by AZT is described in Stein et al.: “AZT, a nucleoside analogue azidothymidine, inhibits the copying of viral RNA genome into complementary DNA by competing with natural nucleotide substrate thus terminating the growing DNA strain.” See Page 115, Introduction. Clearly, the function of AZT is to inhibit the HIV reverse transcription as opposed to the HIV reverse transcriptase. Thus, AZT is NOT a reverse transcriptase inhibitor. The present application is directed to a method for evaluating the effectiveness of an *HIV reverse transcriptase inhibitor*. Therefore, Stein et al. does not teach a method for evaluating HIV reverse transcriptase inhibitor. Further, Stein et al. does not disclose any response or effect resulting from the AZT treatment in the subject containing the reverse transcriptase mutations, which is the focus of the present invention as evidenced by the steps (iii)-(v). In other words, Stein et al. do not disclose the steps (iii)-(v) as recited in the pending claims. Thus, Stein et al. does not disclose each and every element of the pending claims 2 and 5.

Servais et al. discloses a reverse transcriptase of HIV having glycine at position 194. Servais et al. does not teach reverse transcriptase inhibitors nor methods of evaluating a reverse transcriptase inhibitor. Hence, the deficiency in Stein et al. cannot be cured by Servais et al. The *prima facie* case of obviousness have not been met, as neither reference considered teaches or suggests each and every element of claims 2 and 5.

To advance the prosecution, applicants have amended claims 2 and 5 to direct a method of evaluating an HIV reverse transcriptase inhibitor wherein the inhibitor does not include AZT.

Accordingly, the rejection under 35 U.S.C. § 103(a) has been obviated and should be withdrawn.

In view of the foregoing amendment and remarks, allowance of claims 2 and 5 is respectfully requested.

Applicants respectfully request that a timely Notice of Allowance be issued in this case.

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